

ENTERED

October 07, 2022

Nathan Ochsner, Clerk

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

TAMMY PIZZITOLA,
Plaintiff,

v.

ETHICON, INC. and
JOHNSON & JOHNSON,
Defendants.

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CIVIL ACTION NO. 4:20-CV-02256

ORDER

Before the Court is the Motion to Exclude Dr. Vladimir Iakovlev filed by Defendants Ethicon, Inc. and Johnson & Johnson. (Doc. No. 162). Plaintiff Tammy Pizzitola has filed a response in opposition to which the Defendants have replied. (Doc. Nos. 168, 172). The Court hereby **grants** in part and **denies** in part the motion.

I. Legal Standard

Defendants' motion was filed primarily under the principles set in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). *Daubert's* holdings have been summarized as follows:

Reliable testimony must be grounded in the methods and procedures of science and signify something beyond "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786. The inferences or assertions drawn by the expert must be derived by the scientific method. *Id.* In essence, the court must determine whether the expert's work product amounts to "good science." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("Daubert II") (quoting *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786). In *Daubert*, the Supreme Court outlined factors relevant to the reliability prong, including: (1) whether the theory can be and has been tested; (2) whether it has been subjected to peer review; (3) the known or potential rate of error; and (4) whether the theory or methodology employed is generally accepted in the relevant scientific community. *Daubert*, 509 U.S. at 593–94, 113 S.Ct. 2786. The Supreme Court emphasized the "flexible" nature of this inquiry. *Id.* at 594, 113 S.Ct. 2786. As later confirmed in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999): "*Daubert's* list of specific factors neither

necessarily nor exclusively applies to all experts or in every case. Rather the law grants a district court the same broad latitude when it decides how to determine reliability as [the court] enjoys in respect to its ultimate reliability determination.” *Id.* at 141–42, 119 S.Ct. 1167.

Abarca v. Franklin Cty. Water Dist., 761 F. Supp. 2d 1007, 1021 (E.D. Cal. 2011).

While *Daubert* attacks usually focus on a witness’ reliability, some courts have also included an attack on a witness’ qualifications (or lack thereof) under the *Daubert* umbrella. Defendants’ motion concerning Dr. Iakovlev has the elements of both.

II. Prior *Daubert* Rulings of the MDL Court

At the onset, the Court notes that Defendants assert in their motion that both sides have agreed to be bound by the *Daubert* rulings previously made by the MDL Court. (Doc. No. 159). While the parties stipulated to be bound by those rulings for purposes of the trial in this case, each side apparently has tried to reserve the right to appeal those rulings at the appropriate time post-judgment. This, of course, puts this Court in a somewhat interesting position. It can reject this stipulation or accept such stipulation and then later be second-guesses on appeal for a ruling it did not make. While this Court questions whether one can appeal the results of a voluntary stipulation, it accepts the parties’ stipulation.

That being the case, there are various objections contained in Defendants’ motion that this Court need not address as they were already addressed in the MDL and were repeated by the parties here only as a means of preserving the Defendants’ objection to the ruling.

III. Defendants’ Motion

Dr. Iakovlev is an anatomical pathologist and seems to have also spent a good portion of his training in the area of orthopedics. Defendants seeks to limit Dr. Iakovlev’s testimony so that he should not be allowed to testify about:

1. His (“bark”) theory of degradation because:

- a. it has never been tested;
- b. there is no evidence that Prolene mesh degrades in humans;
- c. the medical literature he cites does not support his theory;
- d. it is buoyed by his review of products unrelated to Defendants;
- e. his definition of “degradation” differs from that of the Food and Drug Administration; and

2. Warnings.

IV. Dr. Iakovlev’s Degradation Theory

The Court hereby excludes the Dr. Iakovlev’s degradation theory as far as he attempts to relate this theory to the Plaintiff or any other human being. This Court finds this theory to be unreliable in a number of ways. First, it has never been reliably tested. Second, it is not supported by reliable evidence that Prolene degrades in a human. Third, to the extent Dr. Iakovlev has tested and/or inspected various samples in his laboratory, he cannot reliably relate his findings to either of Defendants’ products or Defendants’ products that have been inserted in the Plaintiff, or that his “bark” theory has ever occurred in any human being.

To the extent the remainder of Dr. Iakovlev’s purported testimony is based upon either a definition of “degradation” and/or clinical studies that Defendants claim do not support his conclusions, the Court overrules the Defendants’ motion. This Court appreciates that the MDL opinion did not compare each of the studies he cites to see whether they actually support the doctor’s opinions, but even the Defendants, in their motion, do not discredit each and every study in such a way that it completely destroys the reliability of some of Dr. Iakovlev’s opinions. While the points raised in this regard may undermine the credibility of his testimony, they do not preclude its admission.

This is the type of “[s]haky but admissible evidence” that must “be attacked by cross examination, contrary evidence and attention to the burden of proof, not exclusion.”

Icon-IP Pty Ltd. v. Specialized Bicycle Components, Inc., 87 F. Supp. 3d 928, 941 (N.D. Cal. 2015) (quoting *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010)). The objections to Dr. Iakovlev’s testimony are overruled.

V. Warning Testimony

With regard to Dr. Iakovlev’s proposed “warning” testimony, Defendants’ primary complaint is that it is both unreliable and that he has no qualifications to so opine. The Defendants correctly point out that a device manufacturer is generally under the burden to adequately warn the end user, which under Texas law is the treating physician (learned intermediary). The Plaintiff, in her response, argues that Dr. Iakovlev is qualified to speak about those warnings because he is knowledgeable about the clinical-pathological effects of the product in question. The Court disagrees. First, the placement/insertion of the device in question is outside his expertise. Second, he has never reviewed the IFU and then counseled a patient awaiting this specific surgery in a clinical setting. Finally, he has never drafted an IFU for a device being inserted in a patient.

Dr. Iakovlev is neither an expert in the legal requirements for an IFU, nor is he a physician who practices in this area of medicine or who is familiar with the standards of practice in either this area of medicine or geographic area. Finally, he has no relevant experience in drafting an IFU. As such, he is not qualified in this arena.

VI. Conclusion

Defendants’ Motion to Exclude Dr. Vladimir Iakovlev is **granted** in part and **denied** in part. The stipulation concerning the prior rulings of the MDL Court is adopted. The motion to

exclude any testimony by Dr. Iakovlev concerning his degradation/bark theory is **granted**. The motion to exclude all legal opinions and conclusions as to the governing appropriate warnings and the appropriate content of an IFU is **granted**.

The motion to exclude as it pertains to Dr. Iakovlev's testimony because it is based in part upon some authoritative studies that may ultimately be distinguishable is denied.

SIGNED at Houston, Texas this 7th day of October, 2022.

A handwritten signature in black ink, appearing to read 'Andrew S. Hanen', written over a horizontal line.

Andrew S. Hanen
United States District Judge